

device's performance or safety specifications or intended uses.

(1) Has FDA appropriately defined the terms, "refurbisher," "as is" remarketers, and "servicers"? If not, what changes to these definitions should be made?

(2) What evidence exists regarding actual problems with the safety and/or performance of remarketed devices that are the result of the remarketing? Specific examples should be submitted.

(3) What is the appropriate level of regulatory controls that should be applied to persons who remarket devices?

(4) Should refurbishers, "as is" remarketers, and servicers be subject to the same or different regulatory requirements?

In addition, FDA is specifically considering whether to propose rulemaking regarding modified registration, listing, and CGMP requirements for these types of remarketers, or whether to make some or all of these three controls voluntary. For example, the agency could propose that refurbishers and/or servicers be required to register and list with FDA (part 807), and comply with certain CGMP requirements, such as quality system requirements (part 820, subpart B), production and process controls (part 820, subpart G), acceptance activities (part 820, subpart H), corrective and preventive action (part 820, subpart J), labeling and packaging control (part 820, subpart K), and records (part 820, subpart M). Alternatively, the agency could propose that refurbishers and/or servicers be required to register and list, but comply only with CGMP requirements for maintaining complaint files (§ 820.198(a)) and conducting failure analyses (§ 820.198(b) and (c)). In making comments relating to the regulatory approaches, comments should indicate whether their comments relate to refurbishers, "as is" remarketers, and/or servicers, as described in section IV of this document. Other regulatory approaches may be proposed by the agency or by the comments which, if implemented, would require the issuance of new guidance documents, or consist of changes to current regulations or changes to existing guidances CPG 7124.28 and CPG 7133.20.

## VI. Comments

The agency will consider any comments submitted in response to this ANPR, or comments relating to the reevaluation of agency guidances, including CPG's 7124.28 and 7133.20. FDA will consider the record of any public meetings or any advisory

committee meetings, along with comments, proposals and other information received, when deciding whether to issue or revise agency guidance or modify any existing regulations.

Interested persons may, on or before March 23, 1998 submit to Dockets Management Branch (address above) written comments regarding this ANPR. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA does not anticipate granting requests for extension to this 90-day comment period.

Dated: December 3, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 52

[PS-158-86]

RIN 1545-AJ23

#### Petroleum Tax Imposed on Natural Gasoline

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Withdrawal of notice of proposed rulemaking.

**SUMMARY:** This document withdraws a proposed regulation relating to the petroleum tax imposed on natural gasoline. The withdrawal affects persons that produce natural gasoline at fractionation facilities or receive natural gasoline produced at those facilities. **FOR FURTHER INFORMATION CONTACT:** Ruth Hoffman, (202) 622-3130 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

Section 4611 imposed a tax on crude oil (including natural gasoline) received at a United States refinery. On April 26, 1993, a notice of proposed rulemaking (PS-158-86) relating to this tax was published in the **Federal Register** (58 FR 21963). The proposed regulation treats any facility that produces natural gasoline by fractionation or similar operation as a United States refinery. Under this rule, tax would be imposed

on natural gasoline when it is produced from natural gas liquids at a fractionation facility.

Since the publication of the proposed regulation, the tax imposed by section 4611 has expired. Because tax is not currently imposed under section 4611, the proposed regulation is being withdrawn. For purposes of section 4611 prior to its expiration, the IRS will follow the result in *Enron Gas Processing Co. v. United States*, 96-1 USTC ¶ 70,058 (S.D. Tex. 1996), in all cases involving substantially similar facts. In *Enron*, the U.S. District Court for the Southern District of Texas held that fractionation facilities are not United States refineries.

#### List of Subjects in 26 CFR Part 52

Chemicals, Excise taxes, Reporting and recordkeeping requirements.

#### Withdrawal of Notice of Proposed Rulemaking

Accordingly, under the authority of 26 U.S.C. 7805, the notice of proposed rulemaking that was published in the **Federal Register** on April 26, 1993 (58 FR 21963) is withdrawn.

**Michael P. Dolan,**

*Deputy Commissioner of Internal Revenue.*

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## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

#### 30 CFR Parts 56, 57, 62, 70, and 71

RIN AA53

#### Health Standards for Occupational Noise Exposure in Coal, Metal and Nonmetal Mines

**AGENCY:** Mine Safety and Health Administration (MSHA), Labor.

**ACTION:** Proposed rule; availability; request for comments.

**SUMMARY:** On December 16, 1997, MSHA published a notice in the **Federal Register** (62 FR 65777) announcing the availability of a report from the National Institute for Occupational Safety and Health (NIOSH) entitled "Prevalence of Hearing Loss For Noise-Exposed Metal/Nonmetal Miners." The Agency further stated its intent to supplement the rulemaking record with this report and to make it available to interested parties upon request.

MSHA received several requests from the mining community that they be provided an opportunity to comment on